CHLAMYDIA SCREENING DECISION STUDY

Janet Rogers

APPROVED:

_____

Chair Date

_____

Member Date

_____

Member Date

APPROVED:

_____

F. G. Abdellah, Ed.D., Sc.D., RN, FAAN Date
Dean

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
MAY 2000	**N/A**	**-**

4. TITLE AND SUBTITLE
CHLAMYDIA SCREENING DECISION STUDY

5a. CONTRACT NUMBER
5b. GRANT NUMBER
5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
JANET ROGERS, BSN

5d. PROJECT NUMBER
5e. TASK NUMBER
5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Uniformed Services University of the Health Sciences

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSOR/MONITOR'S ACRONYM(S)
11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Chlamydia is a prevalent infection among the sexually active. Studies have shown that chlamydia is a health problem for military women. The United States Center for Disease Control recommends screening asymptomatic women under the age of 25. Many studies show that screening asymptomatic young women uncovers significant numbers of infections. Other studies show that many young women are not being screened for this disease. This qualitative study investigates what factors influence providers decisions to screen for chlamydia. A record review of 28 active duty women who received pelvic exams at a military health clinic for chlamydia screening and chlamydia prevalence was performed to enrich the interpretation of the data. Three healthcare providers who perform pelvic exams were interviewed. Data was analyzed guided by using Brooks Theory of Intrapersonal Perceptual Awareness (BTIPA) for factors influencing their decisions to screen for chlamydia. The interviews were studiously reviewed for themes and compared to the themes of perception, judgment, and intrapersonal perceptual awareness in accordance with BTIPA.

15. SUBJECT TERMS
chlamydia; screening; decision making; military

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**SAR**	**67**	

DISCLAIMER STATEMENT

Department of Defense

This work was supported by the Uniformed Services University of the Health Sciences Protocol No. T061AM. The opinions or assertions contained herein are the private opinion of the author and are not to be construed as official or reflecting the views of the Department of Defense or the Uniformed Services University of the Health Sciences.

COPYRIGHT STATEMENT

ABSTRACT

Chlamydia is a prevalent infection among the sexually active. Studies have shown that chlamydia is a health problem for military women. The United States Center for Disease Control recommends screening asymptomatic women under the age of 25. Many studies show that screening asymptomatic young women uncovers significant numbers of infections. Other studies show that many young women are not being screened for this disease. This qualitative study investigates what factors influence providers decisions to screen for chlamydia. A record review of 28 active duty women who received pelvic exams at a military health clinic for chlamydia screening and chlamydia prevalence was performed to enrich the interpretation of the data. Three healthcare providers who perform pelvic exams were interviewed. Data was analyzed guided by using Brooks Theory of Intrapersonal Perceptual Awareness (BTIPA) for factors influencing their decisions to screen for chlamydia. The interviews were studiously reviewed for themes and compared to the themes of perception, judgment, and intrapersonal perceptual awareness in accordance with BTIPA.
Key Words: chlamydia screening decision making military

CHLAMYDIA SCREENING DECISION STUDY

by

JANET ROGERS, BSN

THESIS

Presented to the Graduate School of Nursing Faculty of

The Uniformed Services University of the Health

Sciences in Partial Fulfillment of the

Requirements for the

Degree of

MASTER OF SCIENCE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

May 2000

TABLE OF CONTENTS

LIST OF TABLES

CHAPTER I: INTRODUCTION

Introduction

This chapter introduces the topic of healthcare providers making a decision to screen for chlamydia. It describes the importance of the topic and the relevance to the military.

Background

Chlamydia is a prevalent infection among the sexually active; it is currently the most common sexually transmitted disease in the United States. The United States Center for Disease Control and Prevention (CDC) reports 3 million genital chlamydia infections annually (Eradication, 1998). Many infected women are asymptomatic and if left untreated, chlamydia infection may result in ectopic pregnancies, tubal infertility and pelvic inflammatory disease (Mosure et al., 1997). The annual United States health care costs related to pelvic inflammatory disease and its associated sequela of ectopic pregnancy and infertility exceed $2.6 billion (Washington, Arno, & Brooks, 1986). No more recent studies about the financial costs of chlamydia infection and its sequela could be found, but it is reasonably assumed that healthcare costs have not decreased since 1986 and

presumably, chlamydia infections have not become less expensive.

Due to the asymptomatic nature of chlamydia infection in females, clinicians must maintain a high index of suspicion for this infection even if no apparent signs or symptoms of infection exist. This has relevance to the military as an uncomplicated chlamydia infection can be treated with an inexpensive course of oral antibiotics taken on an outpatient basis, while pelvic inflammatory disease may require medical evacuation from a deployment, with hospitalization costing thousands of dollars. A recent study of female army recruits showed that 93.1% were sexually active and 9.2% were asymptomatically infected with chlamydia (Gaydos et al., 1998). A study by Malone, Hyams, Hawkins, Sharp, and Daniell (1993) found that male U.S. military personnel engage in high risk sexual activities during deployments. It is reasonable to assume that female military personnel may engage in high risk sexual activities under similar situations.

By screening asymptomatic women and providing early intervention for sub-clinical infection, adverse outcomes for chlamydia infection may be minimized. Current professional guidelines (CDC, 1998) recommend routine

screening and treatment if indicated at annual examinations for asymptomatic chlamydia infections for women under 25 years of age, particularly if they have a new partner, or have had more than one sex partner over their lifetime, or inconsistent barrier contraception practice.

Problem Statement

Chlamydia infection is a significant problem for young women. Current professional guidelines recommend screening of asymptomatic women under the age of 25. Several studies have documented that many clinicians do not strictly adhere to these guidelines. The problem is that no one knows what influences clinicians to screen for chlamydia.

There were three purposes to this study. The main purpose of this study was to describe the factors which influence a providers decision to screen for chlamydia in active duty females younger than 25 years of age who are sexually active. Then, in an effort to enrich the findings from interviewing providers about the decision making process; the prevalence of chlamydia screening of active duty, sexually active females under the age of 25 who attend a routine outpatient appointment for the purpose of receiving a pelvic examination was described. Finally, to determine if appropriate screening was being performed, the prevalence of chlamydia infection in this same

population was described.

Research Questions

Based upon the problem statement, the following research questions were asked:

What factors influence clinicians decision to screen for chlamydia?

What is the prevalence of chlamydia screening for the active-duty population?

What is the prevalence of chlamydia among those screened in the active duty population?

Theoretical Framework

There are two theories that formed the basis of this study. The first is Neuman s Systems Model (Meleis, 1991). Neuman proposed that individuals are holistic beings with lines of defense, lines of resistance, basic survival factors, and universal personal variables: physiological, psychological, sociocultural, developmental, and spiritual. All humans experience stressors from the internal environment and the external environment. Stressors challenge the integrity of the individual s health. Nurses assess individual s responses to stressors and assist individuals to prevent further stressing of the individual. Health is compromised when a stressor crosses the lines of

defense. Primary prevention keeps stressors from penetrating lines of defense. Secondary prevention decreases the stressor and enhances wellness. Tertiary defense involves restoring compromised health to an uncompromised or less compromised position.

By screening for disease and intervening early in the disease process, clinicians provide secondary prevention, potentially minimizing the insult in a pre-symptom state. This theory may be used as a foundation of the practice of clinicians screening asymptomatic women to detect sub-clinical infection to minimize the adverse outcomes of untreated chlamydia. Ideally, chlamydia screening would identify all infected women without the undue burden of screening those who are unlikely to be infected.

The theory that explains clinicians decision making is Brooks theory of intrapersonal perceptual awareness (BTIPA). Brooks describes nurses as whole beings who utilize perceptions, judgments, and intrapersonal perceptual awareness to make clinical decisions (Brooks & Thomas, 1997). The nurse-clinician then makes patient care decisions based on perceptions, analysis of perceptions and past experiences. However, nurse-clinicians use more than professional guidelines to provide health care services. Past personal and professional experiences help shape the

analysis of clinicians perceptions and ultimately influence clinical decision making.

Definition of Terms

For the purpose of this study, the following definitions were used:

Routine Pelvic Examination An assessment of the female genitalia that includes a speculum and a bimanual examination performed to evaluate the size, shape, consistency, and tenderness of pelvic organs, may include the collection of biological specimens to test for specific disease conditions, to detect disease in its earliest state and to promote wellness

Active duty female Any female, regardless of branch of service, on active military duty

Chlamydia screening Any lab test collected and performed to diagnose chlamydia trachomatis infection of the genital tract

Clinician A professional health care provider, regardless of educational preparation who has credentials to perform routine pelvic examinations at Walter Reed Army Medical Center (WRAMC), may include M.D., D.O., P.A., and C.R.N.P.

Assumptions and Limitations

Limitations of this study include:

1. Results may not be applicable to other patient populations.
2. The number of records screened may not yield an accurate description of chlamydia screening and affect generalizing findings.
3. There are a variety of chlamydia screening tests available and the specificity and sensitivity of each test method is different, which may affect the reported prevalence of infection.
4. Sampling will be done by convenience methods.
5. Clinicians interviewed may not be representative of all clinicians who do pelvic exams in that clinic or may not be able to verbalize accurately the thought processes used to make decisions.

There are a few basic assumptions underlying this study:

1. Clinicians are assumed to be knowledgeable about screening recommendations for asymptomatic chlamydia infection in women.
2. There will be no logistical issues that limit clinicians from performing chlamydia screening.
3. The laboratory will complete each test that is ordered.

4. Clinicians will be willing to try to accurately recall and articulate what factors influence clinical decision making.

Summary

This chapter introduces the issue of asymptomatic chlamydia infection as a problem for American women. While current professional guidelines recommend screening certain categories of women, it is unknown how clinicians make the decision to screen a woman for chlamydia. The purpose of this study is to describe factors used by clinicians in making that decision.

CHAPTER II: REVIEW OF LITERATURE

Introduction

The purpose of this chapter is to summarize the available literature on genital chlamydia infection in women. Civilian population studies and military population studies are presented. Research that describes clinician decision making is also discussed.

Studies of Civilian Populations

There are several studies that document the prevalence of genital chlamydia infection in sexually active young women. Biro, Rosenthal, and Kiniyalactos (1995) investigated 373 young women aged 12-21 who presented to an urban adolescent clinic for routine pelvic exams or abdominal or pelvic complaints. All were screened for chlamydia, 75 tested positive for a total prevalence rate of 20%. Even though the active duty population is older than the population of this study, this study is important in documenting chlamydia as a health problem for young women.

In a 1992 study of Massachusetts health maintenance organizations (Thrall et al., 1998) sexually transmitted disease test rates were reported on 33,701 enrolled female members aged 15-21. The percentage of adolescent women who were tested for chlamydia and gonorrhea ranged from 2% for

15 year olds to 9% for 21 year olds. Only 11% of 15-19 year olds were tested of the estimated 53% who were sexually active. This study describes screening that is not consistent with current CDC guidelines for screening all sexually active adolescents for chlamydia infection. It lays the groundwork for factors other than professional guidelines that influence clinicians decision to screen for chlamydia.

Universal chlamydia testing of sexually active women (Mosure et al., 1997) who had pelvic exams in public funded family planning clinics in Northwestern states from 1988-92 documented a prevalence rate of 10% over the five years of the study. Over 148,000 tests were performed. Of those infected with chlamydia, 73% had no clinical sign (pelvic inflammatory disease, mucopurulent cervix, or friable cervix). This study is important in describing chlamydia as a problem for adult women, not just adolescents, and in documenting the asymptomatic nature of the infection.

During the same time period (1988-92), the city of Columbus, Ohio conducted a study at a variety of clinical sites, both public and private. All females aged 15-44 who received pelvic exams at study sites were tested for chlamydia. Almost 200,000 specimens were collected. The prevalence of chlamydia in 1989 was 8%, which decreased to

5.4% in 1992 (Mertz et al., 1997). A limitation of this study is that it is unknown if the study participants were tested a single year or multiple years. It is likely that the decrease in prevalence may be due to previously screened women being treated and tested on subsequent years.

Studies of Military Populations

Similar rates of chlamydia infection have been reported among military populations. In 1986 an Army medical center in North Carolina screened every female who received a pelvic exam in the emergency department over a four month period (Pfaff & Pimentel, 1991). The age range of women tested was 16-41. Out of the 326 pelvic exams, 36 chlamydia tests were positive. Over half (56%) were neither treated with antibiotics appropriate for chlamydia infection on release from the emergency department nor referred to gynecology for further evaluation. Additional staff time was used contacting patients for treatment. Even though this population was not asymptomatic this study found chlamydia infection to be a problem within the military community.

A 1991 study of active duty females undergoing routine pap smear exams (Catterson & Zadoo, 1993) described a chlamydia prevalence of 8.2%. Troop medical clinic

providers screened 476 consecutive Army females and had 39 positive results. All patients with positive tests were asymptomatic. Catterson and Zadoo (1993) conducted a relevant study as they found chlamydia infection as a problem for active duty females.

A more recent, larger study (Gaydos et al., 1998) indicates chlamydia infection still is a problem for the military. From January 1996 to December 1997 new female recruits at a basic training post were screened for chlamydia after consenting to be tested. Of 16,593 women who met inclusion criteria, 79.7% agreed to participate. For the entire study population the chlamydia prevalence was 9.2%. For those participants who denied ever having vaginal sex the prevalence was 1.4% (13/914). Only 8.4% of those who always used condom had a positive chlamydia test. Thus, even those women with a health history that would not place them at risk for chlamydia infection, were in fact infected.

Studies of Decision Making

There are fewer studies published on chlamydia screening decision making. Alexander, Treiman, and Clarke (1996) conducted a survey of 1625 certified registered nurse practitioners. Only 611 nurse practitioners responded. Respondents indicated feeling knowledgeable or

very knowledgeable (95%) about chlamydia. Items testing chlamydia knowledge were answered correctly by 60-80%. Nurse practitioners self-reported compliance with CDC guidelines for chlamydia screening at less than 100%. Of the respondents, 67% reported routinely screening sexually active adolescents. Patients who had new partners, or who had multiple partners were routinely screened by 73% and 80%, respectively. Patients who did not use barrier methods were routinely screened by only 34% of respondents. This survey is important because is describes nurse practitioners self-reported knowledge about sexually transmitted diseases and described patient situations in which nurse practitioners were likely to screen patients for chlamydia.

Screening for chlamydia infection can be very costly. In order to reduce the costs, attempts have been made to identify criteria to allow the fewest number of patients to be screened, yet still identifying most of the infection. A study which compared the screening criteria for chlamydia among three different studies (Marrazzo, Fine, Celum, DeLisle, & Hunter, 1997), found that the CDC criteria (all sexually active females under 25, new partner, more than one partner over a lifetime, or inconsistent use of barrier contraception) performed well. This study analyzed

previously published studies that conducted universal screening for chlamydia. They found by screening 58-74% of the women, 88-89% of infections would have been detected. For many patients and practices, the cost of chlamydia screening is a deterrent to universal screening of asymptomatic women.

The San Diego County Department of Health Services surveyed 171 primary-care clinics and group practices that provided reproductive services to women in May of 1993 (CDC, 1994). Information was requested on chlamydia screening, reporting, and diagnosing and treatment practices. Chlamydia screening practices were grouped into protocol screening in which the clinician followed a policy to test women or clinician-directed screening in which the clinician tested based on the patient assessment. 85 providers returned surveys. All respondents reported practicing clinician-directed screening. In addition, protocol screening was performed by 53% in at least one situation. Protocol screening situations were reported as adolescent 39%, gynecological 20%, and initial family planning 33%. Many of the clinics and group practices had no written policy for routine screening of chlamydia the only screening performed was at the clinicians discretion.

In a similar survey of primary-care practices in Wake County, North Carolina (CDC, 1997), 159 surveys were mailed with 127 responses. 117 responses met inclusionary criteria of serving adolescents. Of the respondents, 94 provide chlamydia testing (80%) but only 34 routinely screened adolescents for chlamydia at all or annual pelvic exams (29%). Of the 60 practices that offer testing but do not routinely screen adolescents for chlamydia, all reported testing for chlamydia based upon patient assessment.

In related literature regarding clinical decision making, Callahan, Dittus, and Tierney, (1996) collected data on physicians clinical assessments and the frequency and nature of patients visits in a randomized clinical trial to improve the treatment of late-life depression. Patients who reported symptoms of depression of a screening questionnaire were enrolled in the study. The intervention group of physicians received the scores of the patients depression screening questionnaire along with treatment recommendations. The control group was just as likely as the intervention group to identify patients as being depressed. However, recognizing that a patient was depressed did not consistently result in treatment intentions or actions. There is a gap between the

recognition of depression as a problem and intention to treat or treating the depression. Primary care physicians rely on clinical cues not related to depression severity scales in determining the likelihood of depression. This study describes factors other than objective guidelines that physicians use in making clinical decisions.

Summary

The literature suggests that chlamydia is a prevalent problem among young women, military and civilian. Over several years the prevalence rate seems to be described as 8-12%. Many providers do not utilize protocols but rely upon clinical assessment for chlamydia screening even with a high rate of asymptomatic infection. Providers sometimes recognize potential patient problems but do not have resources or time to investigate if potential problems are actual problems. Physicians rely on clinical cues unrelated to objective criteria in determining the likelihood of disease. After an extensive search of the literature, no study which identified how clinicians make decisions to screen for disease was found. This study begins the description of clinicians decision to screen for chlamydia.

CHAPTER III: METHODS

Introduction

This chapter discusses the methodology used in this study on chlamydia screening decision making. Primarily a qualitative study, some quantitative data was used to assist in the interpretation of the data.

Research Design and Procedures

The purpose of this study was to describe factors which influence healthcare providers decisions to screen for chlamydia. This is a descriptive study designed to describe the perception, judgment and intrapersonal perceptual awareness factors utilized by professional healthcare providers in making decisions to screen for chlamydia.

Qualitative Research

Qualitative research is based on a holistic world view with a few common beliefs: reality is different for each individual and that reality changes over time and what an individual knows has meaning only in specific situations (Burns & Grove, 1997). Investigating individuals current realities and the meanings that individuals give to situations helps the nursing profession to gain insight into holism. In qualitative research practice the emphasis is on the participants telling their own stories and the researcher later identifying the possible meanings within the participants' stories. No attempt is made by the

researcher to influence the story that is told by the participant. The insights that are gained can lead to theory building, theory support, or may refute a nursing theory. Insights gained from qualitative research add to the knowledge of professional nursing and can form the basis for further quantitative research.

Quantitative Research

Quantitative research is conducted in a manner in which the researcher has more interest in gaining specific, measurable results instead of descriptive or exploratory results. Quantitative research is done to discover cause-and-effect relationships, correlational relationships, or to describe phenomena (Burns & Grove, 1997). In developing the research plan, the investigator decides in advance which variables will be studied. The variables that are selected for study may not necessarily be items of significance for either patients or nurses.

Qualitative research forms the very foundation of nursing research: the aim is to describe what a situation is like from the participants point of view: what is significant to the participant.

This study was designed to be a qualitative investigation with a quantitative component to assist in the interpretation of the data. The quantitative data was collected via a review of the records of 28 active duty, sexually active females who received a pelvic exam at WRAMC

women s health clinic. The rank and age of each of the sample population was recorded along with annotation indicating sexual activity, if they were screened for chlamydia and the chlamydia test result.

After obtaining the screening prevalence data, three clinicians from a military women s health clinic, were interviewed to better understand their decisions to screen for chlamydia. The clinicians were interviewed to identify the perception, judgment, and intrapersonal perceptional awareness factors which influence their decision to screen for chlamydia. The factors of perception, judgment and intrapersonal perceptional awareness influencing decision making come from Brooks work (Brooks & Thomas, 1997) and guided the interviews. The interviews were audiotaped and transcribed for studious review of content looking for common themes. The transcripts were reviewed by the principal investigator and a colleague familiar with qualitative research. The methodology for identifying the themes that emerged from the interviews was adapted from Owen s (1989) study in which she used an inductive approach to develop general knowledge about the concept of hope.

Sample

A convenience sample of records was screened. Inclusionary criteria for the records included: female, sexually active, active duty, age 17-25, received a pelvic exam at the participating clinic. Screening took place

until 28 records which met inclusionary criteria were obtained. A sample of 28 was used for descriptive purposes and was not intended to be applicable to populations beyond the sample.

The participants for the qualitative interviews were obtained using purposive sampling. The appropriate leadership at the military medical facility was contacted to ask permission to invite providers to participate in this investigation. After permission was granted, the investigator contacted each eligible clinician who performed pelvic exams on active duty females in the clinic from which the population of records was obtained to explain the study and invite them to participate. The principal investigator met the prospective participants to further explain the study and obtain informed consent (see Appendix A). A time and location convenient for the participant and the investigator was agreed upon for the interview. The small sample, of three providers was sufficient as this is a descriptive study that began to identify factors that are used in making a decision to screen for chlamydia.

Measurement

A tool was created to use to record data for the record review (see Appendix B). A metallic star sticker was placed on the left inside cover of each record that was reviewed to protect against information from the same

patient record from being recorded twice. The tool recorded branch of military service and rank, age, sexual activity, chlamydia screening, chlamydia results, and documentation of other risk factors for chlamydia besides age.

Interview Process

Interviews with clinicians who practice within a military women s health clinic were conducted. All interviews were audiotaped. The participants were asked for permission to tape record their interviews. The researcher bracketed preconceptions before conducting the interviews by maintaining a log of beliefs on chlamydia screening that was reviewed and updated prior to interviews of participants. Ideas that were bracketed included: not done according to CDC guidelines, done if clinician believes the patient is promiscuous or a risk taker, clinicians are uncomfortable discussing risk factors and professional guidelines for screening for chlamydia with patients, done more frequently for enlisted women than officers and for younger women than older, not performed as true screening test but always performed if clinically suspicious, and younger clinicians are more likely to screen than older clinicians.

The investigator spent a few minutes establishing rapport with the participant by making light conversation about current events and the participant’s prior

employment. Demographic data about the participants was collected including educational background, professional experience, and percentage of time spent practicing women s health. When adequate rapport had been established the investigator asked: Are you ready to start the interview? When a positive answer, was received, the participant was reminded that this investigation is on screening for chlamydia in asymptomatic women then, purposive collection of data began.

Broad, open-ended questions were asked to collect information. If the participants made points that needed further clarification, they were asked for more information. Using Brooks theory of intrapersonal perceptual awareness as a guide, these questions were asked of the participants:

1. What perception cues are used to make the decision to screen for chlamydia?
2. How is judgment used in making the decision to screen for chlamydia?
3. What intrapersonal perceptual awareness factors are involved in making the decision to screen for chlamydia?

The following questions were asked to clarify, What perception cues are used to make the decision to screen for chlamydia? :

1a. What subjective information do you use when making the decision to screen for chlamydia?

1b. How does intuition play into your decision to screen for chlamydia?

1c. What visual cues affect your decision to screen for chlamydia?

The following questions were used to clarify answers to: How is judgment used in making the decision to screen for chlamydia? :

2a. What objective information do you use when making the decision to screen for chlamydia?

2b. What pieces of information do you use when making the decision to screen for chlamydia?

2c. What factors inhibit you from screening for chlamydia?

2d. What do you consider when making the decision to screen for chlamydia?

The following questions were asked to clarify answers given to: What intrapersonal perceptual awareness factors are involved in making the decision to screen for chlamydia? :

3a. What past experiences affect your decision to screen for chlamydia?

3b. How do you make the decision to screen for chlamydia?

3c. What influences you to screen for chlamydia?

Following the interview the investigator made field notes recording cues, behaviors, impressions, and perceptions of the participants.

Data Analysis

Descriptive statistics were used to describe the chlamydia screening frequency obtained from the record review. The frequency of chlamydia screening for each age group (18-24) in the study was computed. The frequency of chlamydia infection was calculated.

The audiotapes were transcribed. The investigator reviewed the transcripts for quotes from the participants in making the decision to screen for chlamydia. Two colleagues familiar with qualitative methods also reviewed the transcripts to identify terms. Quotes from the participants that were identified were written onto index cards. The quotes were edited to enhance readability while leaving the content and meaning unchanged. The index cards were given to four readers to sort into categories according to similarities in meaning or feeling. The investigator reviewed each reader s categories for consistency and to identify the number of categories that emerged from the interviews. The meaning of each category was reviewed and labeled. Categories were clustered into themes of similar meanings. Themes that emerged were compared to Brooks (1997) themes of perception, judgment

and intrapersonal perceptual awareness.

Trustworthiness

Trustworthiness is achieved when the research accurately represents the participants experience (Streubert & Carpenter, 1995). Trustworthiness was established by consistent use of the interview questions which asked for answers based on the participants experience. The investigator reviewed the transcripts while listening to the audiotapes to ensure accurate transcription of interviews.

To further verify an accurate representation of the participants experience, a colleague, familiar with qualitative research, also reviewed the transcripts for terms used by the participants in making the decision to screen for chlamydia. The investigator s findings and the colleague s findings were compared for consistency in the identification of terms used in making the decision to screen for chlamydia.

Protection of Human Rights

Institutional Review Board instructions from the Uniformed Services University of Health Sciences and WRAMC were followed. There were minimal, if any, risks involved to the participants. Written consent from the active duty women whose records were reviewed was not obtained. There was no personal contact with them. The form that that was used to collect the data had no information that would be

able to trace the individual in order to provide anonymity. There was a written information paper (see Appendix A) for the interview participants to review prior to agreeing to be interviewed. Privacy was protected by conducting the interview in a location unlikely to be interrupted and by maintaining the audiotapes and transcripts in a secure location. Written consent forms were obtained from each interview participant and a copy was provided to them.

CHAPTER IV: ANALYSIS OF DATA

Introduction

A description of the sample and analysis of the collected data are reported in this chapter. The quantitative data of the prevalence of chlamydia screening and chlamydia infection are presented. The qualitative data includes thematic categories and theme clusters that emerged from interviews with participants.

Description of the Sample

The quantitative sample consisted of a review of medical records of 28 active duty military women under the age of 25 who received a routine pelvic exam at WRAMC gynecology clinic. Over 100 medical records were reviewed to find 28 which met the inclusionary criteria of: active duty, female, under age 25, new or more than one sex partner over a lifetime and inconsistent or no barrier contraceptive use.

The qualitative data was obtained from interviews of three providers in the WRAMC gynecology clinic. The sample included two M.D.s and one D.O. All were active duty Army. The range of experience was 3 to 16 years. Two of the participants were women and one was a man. Two were board certified in Obstetrics and Gynecology and one was in the final year of an Obstetrical and Gynecology residency.

Quantitative Results

Twenty-eight records which met inclusionary criteria

were reviewed. By using CDC guidelines all 28 women should have been screened for chlamydia. Only 3 of the 28 women were screened for chlamydia at the exam. No woman tested positive for chlamydia. Five records had risk factors for chlamydia documented. Four records documented imperfect barrier contraception use. One documented multiple sex partners. Of the five records with risk factors documented, only one (multiple sex partners) was screened for chlamydia.

The median age of women was 23. The mode was age 25, with a range of 18-24. Two of the women who were tested were 23. The other woman who was tested was 22.

All women who were screened for chlamydia or who had risk factors documented were enlisted. Recently published literature (Gaydos et al., 1998) supports chlamydia infection as a health problem for enlisted women. No studies were found investigating chlamydia infection among officers.

Qualitative Results

Terms identified after studious review of transcripts were given to four readers to sort according to similarity of meaning or feeling. Some terms overlap categories. Four theme categories emerged with six theme clusters. Table 1 summarizes them. Following the table a brief description

of each theme is provided along with terms which support the theme.

Table 1. Theme Categories and Theme Clusters

Theme Category 1: Perception of risk
Theme Cluster 1A: Provider perception of risk
Theme Cluster 1B: Patient perception of risk
Theme Category 2: Professional Judgment
Theme Cluster 2A: Following Guidelines
Theme Cluster 2B: Diagnostic Tool
Theme Category 3: Clinician Bias
Theme Category 4: Accessibility

Theme Category 1: Perception of Risk

All clinicians interviewed identified risk as a factor used in their decision making for chlamydia screening. Each identified risk factors and risk behaviors which influenced their decision to screen for chlamydia. In addition, each one mentioned patients who requested to be tested for chlamydia. The following statements illustrate this theme.

Theme Cluster 1A: Provider perception of risk.

A patient that presents with nausea, vomiting, diarrhea, to me has gastroenteritis, unless there is some other reason to think they have PID (pelvic inflammatory disease). Yet, by CDC criteria, they would

probably meet the criteria for PID. Most of them based on the minimal criteria and one major criteria would.

On physical exam, if I saw mucopurulent cervical discharge, then I would screen for chlamydia. If I saw things that might be consistent with other sexually transmitted diseases. For instance, clearly a herpes ulcer, in someone who hadn't had a previous history of herpes. Then, even in the absence of anything else, I would go ahead and do cervical cultures.

If you have a patient who is coming in with a history (of sexually transmitted disease) or you are treating for a sexually transmitted disease, like herpes, I would recommend that patient be screened for other sexually transmitted diseases at the same time. I think that is really important, because, if they have that one, there is a likelihood that they might potentially have another one, like gonorrhea, chlamydia.

Theme Cluster 1B: Patient perception of risk.

A lot of times patients will just come out and ask (to be screened for chlamydia) and if there is any concern that they have been in a relationship that there might have been some infidelity then I will go ahead and ask if they want it done or patients will just come out and ask for it to be done.

Any patients who even have a concern that their partner may have transmitted a sexually transmitted disease to them, I will screen those patients.

Patients' concern that they might have been exposed. A married couple that the wife might be suspicious that the husband has been deployed, has been unfaithful, I would screen in those instances, even if they weren't really certain but they had concerns of their own.

Theme Category 2: Professional Judgment

The clinicians all used guidelines to determine who should be screened for chlamydia. They also used chlamydia screening as a diagnostic tool when they were uncertain of the diagnosis.

Theme Cluster 2A: Following guidelines.

The Army has new guidelines so everyone under the age of 25 gets screened. Prior to that guideline, I followed CDC guidelines. So basically, anyone under the age of 25, had more than one partner, or a new partner, or wasn't using barrier contraception, I would screen for chlamydia.

I would say intuition doesn't play into my decision making because there are high risk populations so I would use that criteria. I pretty much go by standard guidelines, and asking questions.

There is a new guideline of under the age of 25 we screen all comers.

Theme Cluster 2B: Diagnostic tool.

It is a judgment decision. I make a judgment based upon the patient's history that they present to me and decide from there whether or not they need screening to be performed.

Any suspicious history, and a significant physical exam and for IUD (intrauterine device) placement, I will screen them.

If they had symptoms that might be consistent, a yellowish or discolored discharge, pelvic discomfort that's without any GI (gastrointestinal) symptoms, I would screen them.

Theme Category 3: Provider Bias

Each clinician interviewed mentioned situations or groups of patients which are not covered under CDC guidelines.

I am in my fourth year of residency and have been exposed to a lot of patients, so have had a lot of contact with people. So you kind of judge your decision making there.

If they have a history of IV (intravenous) drug use or drug history, then those are patients you are going to screen, you think of those patients.

If I am being consulted by the emergency room and they have me come down to see a patient that they think has PID, I am very frank with them. A lot of times the patient is totally clueless as to why I have been called down there. And I will say to them, "You do understand, I have been asked to come down to see you because they think you have a sexually transmitted disease." And then I will say to them, "Is there any reason I should be thinking you have a sexually transmitted disease?"

Someone who has had a history of it (chlamydia), even if they had it at a young age and it has been a long time. That obviously heightens your awareness about the possibility of either inadequate treatment, or partners not being treated.

Theme Category 4: Accessibility

Two of the participants identified accessibility as a factor in their decision making for chlamydia screening.

> Unless they outright say, please don’t screen me, nothing inhibits me from screening them.

> It is easy to do if you are doing a pelvic exam and you have access to the screening, if you think of it you probably should do it.

Summary

This chapter describes the samples from which the qualitative and quantitative data was obtained. Theme categories and clusters which emerged from the qualitative data are presented. Themes of perception of risk, professional judgment, clinician bias, and accessibility emerged. Clinician bias and professional judgment are related as clinician bias may actually be professional judgment which is not yet supported by research. Accessibility is actually a perception of the provider, as what is perceived to be impossible is inaccessible.

The significance of these findings is that it begins documenting other factors clinicians use besides professional guidelines in making the decision to screen for chlamydia.

CHAPTER V: SUMMARY

Introduction

This chapter discusses the findings of the study. The findings are compared to the theoretical frameworks underlying the study. Implications for practice and for research are discussed.

Discussion

The main purpose of this study was to describe factors used by clinicians in making the decision to screen women for chlamydia. Secondary purposes of the study, describing chlamydia screening prevalence and chlamydia infection were also performed. The prevalence of chlamydia screening and chlamydia infection are used to assist in the interpretation of the findings from the qualitative interviews. Due to the small sample size (n=28), the results of the quantitative data are not applicable to other populations. Even though the qualitative data sample size (n=3) was small, saturation occurred.

The interview participants reported adherence to CDC guidelines. Current professional guidelines (CDC, 1998) recommend routine screening and treatment if indicated at annual examinations for asymptomatic chlamydia infections for women under 25 years of age, particularly if they have a new partner, or have had more than one sex partner over their lifetime, or inconsistent barrier contraception

practice. This view was not supported by the data obtained from the review of patient medical records. Of the sample of 28 medical records that were available for review, only three women were screened for chlamydia, although all met CDC criteria for screening. Of the three women who were screened for chlamydia, none had a chlamydia infection. No attempt was made to correlate the medical records that were reviewed to the clinicians who were interviewed. It is possible that the clinicians who volunteered to participate have a greater knowledge, interest, and comfort level with the topic of chlamydia and screen at a higher rate than their peers. The clinician sample was limited by healthcare facility restraints.

A list of over four hundred patient appointments that met the criteria for inclusion was presented to the outpatient medical records department. From that list only 28 records were available to review. Some of the reasons the number of records available for review was so small include: patients handcarrying the record instead of storing in the records room, permanent change of station orders, and WRAMC is a referral center and military members may have records stored at their primary care facility. Also, it is possible that military members remove clinical documents if they wish to conceal a problem for which they

were seen by a clinician.

Most of the participants' statements regarded testing symptomatic women for chlamydia, not screening for subclinical disease. Perhaps they do not wish to discuss screening for subclinical disease because it is not their practice.

Theoretical Framework

The following themes emerged from this study: perception of risk, professional judgment, clinician bias, and accessibility. These themes support BTIPA findings of decision making being influenced by perception, judgment, and intra-personal perceptual awareness. Accessibility is a theme not identified by Brooks but it may fall under intra-personal perceptual awareness for example, if a clinician does not have knowledge, experience, skills, or necessary supplies/equipment to provide a specific healthcare task, the clinician may blind himself to the possibility of that healthcare task. Although not a perfect match, this study supports BTIPA for clinical decision making consisting of perception, judgment, and intrapersonal perceptual awareness.

Neuman's Systems Theory explains the rationale for screening for sub-clinical disease. By screening for disease and intervening early in the disease process,

clinicians provide secondary prevention, potentially minimizing the insult in a pre-symptom state. This theory may be used as a foundation of the practice of clinicians screening asymptomatic women to detect sub-clinical infection to minimize the adverse outcomes of untreated chlamydia. Although, the clinicians' quotes indicated support for disease screening, the quantitative data did not support this. Therefore, no clear conclusions should be made.

Implications for Practice

Clinicians should be aware that even if they are knowledgeable of current professional guidelines, there are other factors that are involved in making clinical decisions. Perception and judgment form the basis of making a diagnosis: the history and physical exam. Clinician bias may lead to unnecessary diagnostic testing or not testing when appropriate.

Accessibility of diagnostic tools is always a consideration if the clinician is uncertain of the diagnosis. Therefore, administrators must allocate adequate resources, both time and financial, to allow screening for chlamydia in vulnerable populations. Facility policies should support the universal screening of at-risk women according to current professional guidelines.

This study only begins to describe decision making of

clinicians for chlamydia screening. Other studies should be done to gain even further knowledge of how that decision is made.

Clinicians require education on a continuing basis. CDC guidelines change over time. Continuing professional education on current professional guidelines is an important area for clinicians.

Recommendations for Further Research

Very little published material exists on clinical decision making. This study just begins to explore information regarding clinical decision making. Certainly, this study should be replicated with larger sample sizes and in different populations, both military and civilian. There are many other situations besides chlamydia screening that require clinical decision making. Studies that investigate clinical decision making for other patient care scenarios should be performed especially relative to published standards. Ideally, this study would be replicated at a military installation where a large number of young women are serving on active duty. Clinicians who see a large number of patients who are in the at-risk population may have different themes which underlie their practice.

The number of records that were available to review limits the applicability of this study. A study on military members medical records should be done. There are

many issues that are still unknown regarding military health records. An electronic search in multiple medical databases found no studies on military health records. The following are some potential research topics: what issues influence a member s decision to handcarry records or file in records room, how satisfied are members with the records room, what concerns do members have with patient confidentiality.

Summary

This chapter includes a discussion of the findings, a discussion of the support for Neuman’s Systems Theory and BTIPA, implications for practice and implications for further research.

REFERENCES

Alexander, L.L., Treiman, K. & Clarke, P. (1996). A national survey of nurse practitioner chlamydia knowledge and treatment practices of female patients. Nurse Practitioner, 21, 50-54.

Biro, F. M., Rosenthal, S.L. & Kiniyaloctos, M. (1995). Gonococcal and chlamydia genitourinary infections in symptomatic and asymptomatic adolescent women. Clinical Pediatrics, 34, 419-423.

Brooks, E.M. & Thomas, S. (1997). The perception and judgment of senior baccalaureate student nurses in clinical decision making. Advances in Nursing Science, 19, 50-69.

Burns, N., & Grove, S. K. (1997). The practice of nursing research: Conduct, critique, & utilization. Philadelphia: W. B. Saunders.

Callahan, C. M., Dittus, R. S., & Tierney, W. M. (1996). Primary care physicians medical decision making for late life depression. Journal of General Internal Medicine, 4, 218-25.

Catterson, M. L., & Zadoo, V. (1993). Prevalence of asymptomatic chlamydia cervical infections in active duty Army females. Military Medicine, 158, 618-619.

Centers for Disease Control and Prevention. (1994).

Chlamydia prevalence and screening practices- San Diego, CA, 1993. Morbidity and Mortality Weekly Report, 43, 366-375.

Centers for Disease Control and Prevention. (1997). Chlamydia screening practices of primary care providers- Wake County, North Carolina, 1996. Morbidity and Mortality Weekly Report, 46, 819-822.

Centers for Disease Control and Prevention. (1998). 1998 Guidelines for treatment of sexually transmitted diseases. Morbidity and Mortality Weekly Report,47, 8,53-59.

Eradication efforts fail to stop STDs in cities. (1998, December 7). USA Today, p. D8.

Gaydos, C. A., Howell, M.R., Pare, B., Clark, K., Ellis, D. A., Hendrix, R.M., Gaydos, J.C., McKee, K.T., & Quinn, T.C. (1998). Chlamydia Trachomatis infections in female military recruits. The New England Journal of Medicine, 339, 739-744.

Malone, J.D., Hyams, K. C., Hawkins, R.E., Sharp, T.W., & Daniell, F.D. (1993). Risk factors for sexually transmitted disease among deployed U.S. military personnel. Sexually Transmitted Diseases, 20, 294-298.

Marrazzo, J. M., Fine, D., Celum, C. L., DeLisle, S., & Handsfield, H. H. (1997). Selective screening for

chlamydial infection in women: A Comparison of three sets of criteria. Family Planning Perspectives, 170, 158-162.

Meleis, A. I. (1991). Theoretical nursing: Development and progress. Philadelphia: Lippincott.

Mertz, K. J., Levine, W. C., Mosure, D. J., Berman, S. M., & Dorian, K. J. (1997). Trends in the prevalence of chlamydia infection. The impact of community-wide testing. Sexually Transmitted Diseases, 24, 169-175.

Mosure, D.J., Berman, S., Fine, D., DeLisle, S., Cates, W., & Boring, J.R. (1997). Genital chlamydia infections in sexually active female adolescents: Do we really need to screen everyone? Journal of Adolescent Health, 20, 6-13.

Owen, D.C. (1989). Nurses perspectives on the meaning of hope in patients with cancer: A Qualitative study. Oncology Nursing Forum, 16, 75-79.

Pfaff, J. A. & Pimentel, L. (1991). Chlamydial antigen testing on female patients presenting to the emergency department. Military Medicine, 7, 362-4.

Thrall, J. S., McCloskey, L., Spivak, H., Ettner, S. L., Tighe, J. E., & Emmans, S. J. (1998). Performance of Massachusetts HMO’s in providing Pap smear and sexually transmitted disease screening to adolescent females. Journal of Adolescent Health, 22, 184-189.

Streubert, H. J. & Carpenter, D. R. (1995). Qualitative

Research in Nursing: Advancing the Humanistic Imperative. Philadelphia: Lippencott.

Washington, A.E., Arno, P.S., & Brooks, M.A. (1986). The economic costs of pelvic inflammatory disease. Journal of the American Medical Association, 255, 1735-1738.

BIBLIOGRAPHY

Abel, E., Hilton, P., & Miller, I. (1996). Sexual risk behavior among urban women of child bearing age: Implications for clinical practice. Journal of the American Academy of Nurse Practitioners, 8, 115-123.

American Public Health Association (1995). Control of Communicable Disease Manual. Washington, D.C: APHA.

Cates, J.R., Alexander, L., & Cates, W. (1998). Prevention of sexually transmitted diseases in an era of managed care: The Relevance for women. Women's Health Issues, 8, 169-186.

Centers for Disease Control and Prevention (1997). Chlamydia Trachomatis genital infection- United States, 1995. Morbidity and Mortality Weekly Report, 46, 193-198.

Ellen, J. M., Kohn, R. P., Bolan, G. A., Shibowski, S., & Krieger, N. (1995). Socioeconomic differences in sexually transmitted disease rates among Black and White adolescents, San Francisco, 1990 to 1992. American Journal of Public Health, 85, 1546-1548.

Ferreira, N. (1997). Sexually transmitted chlamydia trachomatis. Nurse Practitioner Forum, 8, 70-76.

Gershman, K. A. & Barrow, J. C. (1996). A tale of two sexually transmitted diseases: Prevalence and predictors of chlamydia and gonorrhea in women attending Colorado family

planning clinics. Sexually Transmitted Diseases, 23, 481-487.

Han, Y., Coles, F. B., & Hipp, S. (1997). Screening criteria for Chlamydia Trachomatis in family practice clinics: Accounting for prevalence and clients' characteristics. Family Planning Perspectives, 29, 163-166.

Hillis, S. D., Nakashima, A., Marchbanks, P. A., Addiss, D.G., & Davis, J. P. (1994). Risk factors for recurrent Chlamydia Trachomatis infection in women. American Journal of Obstetrics and Gynecology, 170, 801-806.

Middleman, A. B., Binns, H. J., & Durant, R. H. (1995). Factors affecting pediatric residents intentions to screen for high risk behaviors. Journal of Adolescent Health, 17, (106-12).

Miller, W. C. (1998). Screening for chlamydial infection. A model program based on prevalence. Sexually Transmitted Diseases, 25, 201-10.

Mosure, D. J., Berman, S., Kleinbaum, D., & Holloran, M. E. (1996). Predictors of Chlamydia Trachomatis infection among adolescents: A longitudinal analysis. American Journal of Epidemiology, 144, 997-1003.

Public Health Service. (1990). Healthy people 2000: National health promotion and disease prevention

objectives. Washington D.C: U.S. Government Printing Office.

Rosenberg, A. L. (1997). Sexually transmitted disease screening in women. The Nurse Practitioner, 22, 15-16.

APPENDICES

Appendix A: Informed Consent

Appendix B: Data Collection Tool

Appendix C: Institutional Review Board Approval of Protocol

Appendix D: Clinical Investigations Committee Approval

APPENDIX A: Infomed Consent

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you. If future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

A PHOTOCOPY OF THIS FORM MUST BE SIGNED BY ALL VOLUNTEERS.
Approved by the WRAMC HUCRB on 9/14/99 (Exc) for WU # 1580-99
This form replaces the previous version approved on N/A

PART A(1) – VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____, SSN _____

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal representative for _____ to participate in _____

Chlamydia Screening Decision Study

under the direction of Janice Agazio, LTC, AN

conducted at WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

Janice Agazio, LTC, AN (or her designee), Nursing Research Service, 202-782-7025

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

CENTER JUDGE ADVOCATE OFFICE – (202) 782-1550 or DSN 662-1550

at WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001

[Name, Address and Phone Number of Hospital (Include Area Code)]

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I /the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I/the person I represent is otherwise entitled.

LIMITATIONS TO MEDICAL CARE ARE DESCRIBED IN PART B

PART A (2) – ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____, SSN _____ having full capacity to assent and having attained my _____ birthday, do hereby volunteer for _____ to participate in _____

under the direction of _____

Conducted at WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001

(Name of Institution

(Continue on Reverse)

PART A(2) – ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd)

The implications of my voluntary participation; the nature, duration, and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

CENTER JUDGE ADVOCATE OFFICE - (202) 782-1550 OR DSN 662-1550

at WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC 20307-5001

[Name, Address, and Phone Number of Hospital (Include Area Code)]

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

LIMITATIONS TO MEDICAL CARE ARE DESCRIBED IN PART B

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: (Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 7-2

DESCRIPTION OF THIS STUDY

You are being asked to be in this research study because you provide healthcare to women. Your participation is voluntary. Refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled.

The purpose of the study is to identify factors that healthcare providers use in making the decision to screen young women for chlamydia infection.

Other studies have shown chlamydia is a prevalent disease yet many at-risk women are not screened for chlamydia.

If you agree to be in this study, you will be asked to provide some basic demographic information about yourself and participate in a tape recorded interview in which the primary investigator will ask you questions about how you make the decision to screen a young woman for chlamydia.

AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY

You will be part of this study for a total of one day. The primary investigator will visit you at your workplace and the visit will last about thirty minutes.

Approved by the WRAMC HUC/IRB on 9/14/99 (CJ) for WU #7580-99
This form replaces the previous version approved on N/A
C.J.

I do ☐ do not ☐ (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

PART B – TO BE COMPLETED BY INVESTIGATOR (Cont'd)

POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

There are no expected risks or discomforts from being in this study.

POSSIBLE BENEFITS OF BEING IN THIS STUDY BEING IN THIS STUDY

You will not benefit from being in this study.

CONFIDENTIALITY (PRIVACY) OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep records of your being in this study. These records may be looked at by people from the Walter Reed Department of Clinical Investigation, the Walter Reed Human Use Committee, the Uniformed Services University of Health Sciences, and other government agencies as part of their duties. These duties include making sure that research subjects are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws. Your name will not appear in any published paper or presentation related to this study.

CONDITIONS UNDER WHICH YOUR TAKING PART IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you become ineligible for medical care at military hospitals.

ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for being in this study.

COMPENSATION TO YOU IF INJURED AND LIMITS TO YOUR MEDICAL CARE

Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost to you. You will not receive any compensation (payment) for injury. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care.

A PHOTOCOPY OF THIS FORM MUST BE SIGNED BY ALL VOLUNTEERS.
Approved by the WRAMC HUC/IRB on 9/14/99 (csc) for WU # 7580-99
C.F. This form replaces the previous version approved on N/A

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

PART B – TO BE COMPLETED BY INVESTIGATOR (Cont'd)

ELIGIBILITY OF FEDERAL GOVERNMENT EMPLOYEES TO BE IN THIS STUDY

Your time spent being in this study during your regularly scheduled workday is considered constructive duty and straight time rates will apply; no additional financial compensation will be provided.

By signing below, you acknowledge that you are DEERS-eligible and may make no claim against the Government other than under present laws.

(Signature Required)
SIGNATURE OF VOLUNTEER DATE

(Signature Required)
SIGNATURE OF VOLUNTEER'S SUPERVISOR DATE

WHAT WILL HAPPEN IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the principal investigator as soon as possible. By leaving this study at any time, you in no way risk losing your right to medical care. Any information or tape recordings will be destroyed should you choose to withdraw from the study.

Please feel free to ask any questions that will allow you to clearly understand this study.

A copy of this consent form will be provided to you.

A PHOTOCOPY OF THIS FORM MUST BE SIGNED BY ALL VOLUNTEERS.
Approved by the WRAMC HUC/IRB on 9/14/99 (Cic) for WU # 7560-99
C.J. This form replaces the previous version approved on N/A

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

APPENDIX B: Data Collection Tool

Appendix B

Case	Service	Grade	Sexually .active	Risk factor	Age	Chlamydia screened	Chlamydia Results

Key for Record Review

A= Army
AF= Air Force
N= Navy/Marine
CG= Coast Guard
B= Inconsistent or no use of barrier contraceptives
M= More than one sex partner over lifetime
P= New sex partner
+= Chlamydia results positive
-= Chlamydia results negative
?= Chlamydia results not available

APPENDIX C: USUHS IRB Approval

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
F. EDWARD HEBERT SCHOOL OF MEDICINE
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799

July 20, 1999

MEMORANDUM FOR CAPT JANET ROGERS, GRADUATE SCHOOL OF NURSING

SUBJECT: IRB Approval of Protocol **T061AM** for Human Subject Use

Your research protocol entitled ***"Chlamydia Screening Decision Study,"*** was reviewed and approved for execution on 7/19/99 as an **exempt** human subject use study under the provisions of 32 CFR 2 19.10 1 (b)(2)(4). This approval will be reported to the full IRB scheduled to meet on 12 August 1999.

The purpose of this study is to investigate what factors influence healthcare providers' decisions to screen for chlamydia. This study involves a record review at a military health clinic to determine the prevalence of chlamydia screening and positive diagnosis, as well as interviews of 5-8 healthcare providers who perform pelvic exams to assess their perception, judgement, and intrapersonal perceptual awarness factors used to determine whether to screen for chlamydia. The IRB understands that no subject identifying information will be collected as part of the record reviews or the interviews and that all interview recordings will be destroyed at the conclusion of the study,

Please notify this office of any amendments you wish to propose and of any untoward incidents which may occur in the conduct of this project. If you have any questions regarding human volunteers, please call me at 301-295-3303.

Richard R. Levine, Ph.D.
LTC, MS, USA
Director, Research Programs and
Executive Secretary, IRB

Cc: Director, Grants Administration

APPENDIX D: WRAMC CIC Approval

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO ATTENTION OF

MCHL-CI (40-38a) 10 November 1999

MEMORANDUM FOR LTC Janice Agazio, AN, Nursing Research Service, Walter Reed Army Medical Center, Washington, DC 20307-5001

SUBJECT: Approval to Begin Protocol **Work Unit #7580-99:** Chlamydia Screening Decision Study

1. Congratulations! Your protocol was approved by the Clinical Investigation Committee (CIC) on 14 September 1999 as a "minimal risk" human use protocol and has been assigned Work Unit # 7580-99. Required revisions were received on 14 October, 1 November and 10 November 1999. A copy of the minutes from the applicable committee and a final copy of the research protocol are attached for your administrative files. **Also. enclosed are the approved consent forms that must be duplicated and used for enrolling subjects.** You may begin work on the project upon receipt of this letter. Your research protocol was approved for an enrollment of up to 50 patients and up to 8 health care providers.

2. No Funding was requested for this protocol.

3. This approval is only for **one year.** As part of your continuing review and re-approval, you are required to submit an annual progress report (APR) in the first week of **September each year as** long as your protocol is ongoing.

4. As the principal investigator, you are required by WRAMC 70-1 and other Federal regulations to submit the following in a timely fashion to the Department of Clinical Investigation: (a) addenda delineating any changes in the protocol, (b) notification of serious or unexpected side effects within 24 hours, and (c) annual progress reports for continuing review.

5. **Also enclosed is a copy of the WRAMC Multiple Project Assurance that all investigators agree to adhere to in conducting research, as attested to by your submission of a signed Principal Investigator Responsibilities Statement.** If you have any questions, the POC is Mrs. Cheryl D. Jackson at 782-7848.

Audrey S. Chang

3 Encls
as

AUDREY S. CHANG
Ph.D., DAC
Chief, Research Review Service
Department of Clinical Investigation

CF: Research Administration Service